UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,104	11/10/1999	ASGEIR SAEBO	CONLINCO-040	8881

23535 7590 05/17/2005

MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/438,104	SAEBO ET AL.	
	Examiner	Art Unit	
	Dwayne C. Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06JAN2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 7-24 are pending.

2. Claims 7-24 are rejected.

Response to Arguments and Declaration

3. Applicant's arguments and declaration filed January 6, 2005 have been fully considered but they are not persuasive with respect to Cain et al. Applicant's appellant and the Inventor in the declaration present the following points of issue. First, applicants submit that the Office is citing Cain et al. for a claim limitation as to which Cain et al. is silent, namely that the presence of 11,13-octadecadienoic acid and 8,10-octadecadienoic acid isomers are present in the CLA composition in peak area percentages less than 1%. Second, applicants allege that the Office has not provided evidence or reasoning as to why one skilled in the art would either (a) not believe the evidence contained in the Saebo Declaration or (b) believe that the process used by Cain would not also produce the 8,10 and 1,13 isomers of CLA. Third, applicants suggest that the silence of Cain et al. concerning the presence of the isomers cannot be equated with the absence of the isomers. Fourth, Cain et al. do not teach a solution to the problem of unwanted isomers in CLA compositions. Fifth, the Office action allegedly provides no support for the statement of the declaration that is directed to the coelution "could very well give different ratios of the isomers and thus fall within the instantly claimed ranges." Sixth, applicants next argue that the Office Action of October 1, 2004

does not provide evidence that the double bonds of CLA are sigmatropic systems and that the reaction to obtain CLA could be controlled to the extent necessary to produce the claimed compositions.

4. First, applicants submit that the Office is citing Cain et al. for a claim limitation as to which Cain et al. is silent, namely that the presence of 11,13-octadecadienoic acid and 8,10-octadecadienoic acid isomers are present in the CLA composition in peak area percentages less than 1%. Cain et al. teach of compositions of conjugated linoleic acid that are used in food products for both animals and humans, (see page 1). Cain et al. teach of a 91.8% conjugated linoleic acid product of which 49.7% was the cis 9, trans 11-isomer and 50.3 % was the trans 10, cis 12-isomer, (see Example 1). Clearly, from this cite, Cain et al. has met the requirements that are claimed in the instant invention. Although Cain et al. do not specifically discuss peak area percentages of the isomers of 11,13-octadecadienoic and 8,10-octadecadienoic acid, it would have been obvious to one having ordinary skill in the art that these isomers would be less than 1% of a peak area because Cain et al. teach of a conjugated linoleic acid composition product of which 49.7% was the cis 9, trans 11-isomer and 50.3 % was the trans 10, cis 12-isomer, which adds up to 100.0 % of the CLA, thus there is less than 1% of any other isomer of CLA other than cis 9, trans 11-isomer and the trans 10, cis 12-isomer pf CLA. Furthermore, the prior art reference of Cain et al. specifically state that of the eight geometric isomers of CLA the isomers of c9, t11 and t10, c12 are the most abundant with about equal concentrations. Cain et al. provide motivation to the skilled artisan to decrease the production of the isomers, which includes 11,13-octadecadienoic acid and

8,10-octadecadienoic acid, and even trans-trans-octadecadienoic acid, with the following statement that the, "two most abundant isomers [c9, t11 and t10, c12] are responsible for the beneficial effects of the compositions containing CLA's, (see page 1, lines 8-11 and 20-25). The skilled artisan is provided with the clear motivation to decrease production of undesired CLA isomers, thus producing compositions of the desired c9, t11- and t10, c12-isomers of CLA.

5. Second, applicants allege that the Office has not provided evidence or reasoning as to why one skilled in the art would either (a) not believe the evidence contained in the Saebo Declaration or (b) believe that the process used by Cain would not also produce the 8,10 and 1,13 isomers of CLA. These allegations are not found persuasive because one having ordinary skill in the art is clearly provided with the necessary information and clear teaching that the, "two most abundant isomers [c9, t11 and t10, c12] are responsible for the beneficial effects of the compositions containing CLA's, (see page 1, lines 8-11 and 20-25), which provides motivation to decrease other isomers, namely the 11,13-octadecadienoic acid and 8,10-octadecadienoic acid isomers. One skilled in the art would be flawed if they disregarded this teaching to increase or augment the concentration of the desired and , "two most abundant isomers [c9, t11 and t10, c12] are responsible for the beneficial effects of the compositions containing CLA's. The fact still remains that Cain et al. teach of a composition with a fatty acid distribution as determined by FAME GC of a product that contains 91.8 % conjugated linoleic acid of which is 49.7% was the c9,t11 isomer and 50.3 % was the t10,c12 isomer, (see page 11, Example 1), which adds up to 100.0 % of the CLA, thus there is less than 1% of any

other isomer of CLA other than cis 9, trans 11-isomer and the trans 10, cis 12-isomer pf CLA. Cain et al. even present their data to 0.1 % accuracy, which further supports the fact that the instant claims are clearly rendered obvious in view of Cain et al.

6. Third, applicants suggest that the silence of Cain et al. concerning the presence of the isomers cannot be equated with the absence of the isomers. However, the prior art reference of Cain et al. specifically provide the skilled are artisan with the following explicit teachings, the, "two most abundant isomers [c9, t11 and t10, c12] are responsible for the beneficial effects of the compositions containing CLA's, (see page 1, lines 8-11 and 20-25), which provides motivation to decrease other isomers, namely the 11,13-octadecadienoic acid and 8,10-octadecadienoic acid isomers. One skilled in the art would be flawed if they disregarded this teaching to increase or augment the concentration of the desired and , "two most abundant isomers [c9, t11 and t10, c12] are responsible for the beneficial effects of the compositions containing CLA's.

7. Fourth, Cain et al. do not teach a solution to the problem of unwanted isomers in CLA compositions. Applicant are not giving weight to the explicit teachings of Cain et al. that are directed to the fact that the, "two most abundant isomers [c9, t11 and t10, c12] are responsible for the beneficial effects of the compositions containing CLA's, (see page 1, lines 8-11 and 20-25), which provides motivation to decrease other isomers, namely the 11,13-octadecadienoic acid and 8,10-octadecadienoic acid isomers. The skilled artisan is provided with the clear motivation to decrease production of undesired CLA isomers, thus producing compositions of the desired c9, t11- and t10, c12-isomers of CLA. In fact, Cain et al. provide evidence of this preferred and desired

composition of obtaining higher concentrations of the desired c9, t11- and t10, c12-isomers of CLA with a conjugated linoleic acid (CLA) composition, which has 91.8% of CLA, which is further broken down into 49.7% was the 9,11-isomer and 50.3% was the 10,12-isomer, (see page 11, lines 14-17).

8. Fifth, the Office action allegedly provides no support for the statement of the declaration that is directed to the coelution "could very well give different ratios of the isomers and thus fall within the instantly claimed ranges." This allegation is not found persuasive because one having ordinary skill in the art is clearly provided with the necessary information and clear teaching that the, "two most abundant isomers [c9, t11 and t10, c12] are responsible for the beneficial effects of the compositions containing CLA's, (see page 1, lines 8-11 and 20-25), which provides motivation to decrease other isomers, namely the 11,13-octadecadienoic acid and 8,10-octadecadienoic acid isomers. One skilled in the art would be flawed if they disregarded this teaching to increase or augment the concentration of the desired and , "two most abundant isomers [c9, t11 and t10, c12] are responsible for the beneficial effects of the compositions containing CLA's. The fact still remains that Cain et al. teach of a composition with a fatty acid distribution as determined by FAME GC of a product that contains 91.8 % conjugated linoleic acid of which is 49.7% was the c9,t11 isomer and 50.3 % was the t10,c12 isomer, (see page 11, Example 1). Cain et al. even present their data to 0.1 % accuracy, which further supports the fact that the instant claims are clearly rendered obvious in view of Cain et al. In addition, the declaration specifically states in an affidavit that even applicant acknowledges that there is ambiguity with the co-elution

between t8, c10 isomer and the c9, t11 isomer of CLA with the phrase, "but almost always occurs in a one to one proportion." Furthermore, the data set forth by Saebo in the declaration that was proffered to obviated prior art teachings, lacks the probative force accorded data generated by independent, disinterested parties. For these reasons, this admission plus the fact that this declaration lacks probative force allows for variances with the co-elution of these isomers that could very well give different ratios of the isomers and thus fall within the instantly claimed ranges.

9. Sixth, applicants next argue that the Office Action of October 1, 2004 does not provide evidence that the double bonds of CLA are sigmatropic systems and that the reaction to obtain CLA could be controlled to the extent necessary to produce the claimed compositions. The fact remains that sigmatropic reactions are well known in the art as reactions that are controlled by molecular orbital symmetry characteristics. The previous analysis of sigmatropic rearrangement was abstracted directed from prior art sources, namely Solomons and Carey. In particular, applicants state that Solomons and Carey are silent to sigmatropic rearrangement of a particular class of conjugated bond systems of octadecadienoic acid. However, this statement is irrelevant because these sources, as do other prior art references and journals and textbooks, provide the skilled artisan with the necessary and general information to avoid the generation of undesired side products caused by increased thermal energy. Prior art sources such as these provide the skilled artisan with the general principles to be applied in similar or related systems. It would have been obvious to the skilled artisan in organic chemistry to utilize these well-established Woodward-Hoffmann Rules in conjugated systems,

such as CLAs, artisan to decrease the temperatures in order to control the production of the sigmatropic products, namely the 8,10- and 11,13-octadecadienoic acid isomers. Moreover, applicants are claiming product claims not process of making claims and so the prior art reference of Cain et al. clearly renders the instantly claimed subject matter obvious. Accordingly, one having ordinary skill in the art at the time of the invention is provided with the necessary skills and teachings from these well established sets of Woodward-Hoffmann Rules in conjugated systems, which obviously embraces systems such as CLAs, to decrease the temperatures in order to control the production of the sigmatropic products, namely the 8,10- and 11,13-octadecadienoic acid isomers. In addition, the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Information Disclosure Statement

10. Again, it is respectfully requested any documents, in particular the two references presented in the response of November 22, 2000 on page 3 of 3, that are furnished to the Office by listed on an information disclosure statement to ensure that they are properly reviewed and considered.

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. The rejection of claims 7-24 under 35 U.S.C. 103(a) as being unpatentable over Cain et al. of WO 97/18320 is maintained and repeated. Cain et al. teach of compositions of conjugated linoleic acid that are used in food products for both animals and humans, (see page 1). Cain et al. teach of a composition that contains 91.8% conjugated linoleic acid product of which 49.7% was the cis 9, trans 11-isomer and 50.3 % was the trans 10, cis 12-isomer, (see Example 1). In addition, Cain et al. teach of alky esters of these conjugated linoleic acids (see Examples 1 and 3) as well as conjugated linoleic acid triglycerides, (see Example 8). Cain et al. also teach of utilizing the characterization method of HPLC as well as GC (see Example 8). Although Cain et al. do not specifically discuss peak area percentages of the isomers of 11,13-octadecadienoic and 8,10-octadecadienoic acid, it would have been obvious to one having ordinary skill in the art that these isomers would be less than 1% of a peak area because Cain et al. teach of a conjugated linoleic acid composition product of which 49.7% was the cis 9, trans 11-isomer and 50.3 % was the trans 10, cis 12-isomer. Accordingly, Cain et al. teach of a composition which contains a total of 100 % of both the isomers of cis 9, trans 11-isomer and which would obviously exclude any other isomers, including but not limited to 11,13-octadecadienoic and 8,10-octadecadienoic acid. In addition, Cain et al. teach of utilizing the characterization method of HPLC as

well as GC, which are known to present data results of analyzed products as percentages based on peak areas. Accordingly, it would have been obvious to one having ordinary skill in the art to express the isomers of conjugated linoleic acid as peak area percentages especially when the prior art reference of Cain et al. teach of using the characterization techniques of HPLC and GC, (see the Examples of Cain et al.)

Obviousness-type Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. The provisional rejection of claims 8, 9, 11, 12, 14, 15, 17, 18, 20, 21, and 22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/623,825 is maintained and repeated. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application No. 10/623,825 teach of esters and triglycerides of octadecadienoic acids that have c9,t11- and t10,c12-octadecadienoic acid contents greater than 50% and a content of

8,10- and 11,13-octadecadienoic acid isomers less than 5%, which embraces the instantly claimed 1%.

15. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. The provisional rejection of claims 7-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 8 of copending Application No. 09/132,593 is maintained and repeated. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application No. 09/132,593 teach of esters and triglycerides of compositions of octadecadienoic acids that have c9,t11- and t10,c12-octadecadienoic acid contents greater than 50% and a content of 8,10- and 11,13-octadecadienoic acid isomers less than 2%, which embraces the instantly required 1% limitation. In addition, copending Application No. 09/132,593 teaches of food products of these compositions.

17. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. The provisional rejection of claims 8, 9, 11, 12, 14, 15, 17, 18, 20, 21, and 22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 and 13-17 of copending Application No. 09/271,024 is maintained and repeated. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention as well as copending Application No. 09/271,024 teach of composition of esters and glycerides of

octadecadienoic acid that have contents of at least 30% c9,t11- and t11,c12-octadecadienoic acid and less 1% of 8,10- and 11,13 octadecadienoic acids. In addition, copending Application No. 09/271,024 593 teaches of food products of these compositions.

19. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-

0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see http://pair-direct.uspto.gov. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

DWAYNE JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
May 10, 2005